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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/622,800 | 07/18/2003 | Roman Turovskiy | 412692001700 | 3485 |

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| EXAMINER | |
|---|---|
| VRETTAKOS, PETER J | |
| **ART UNIT** | **PAPER NUMBER** |
| 3739 | |

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/622,800 | TUROVSKIY ET AL. | |
| | Examiner | Art Unit | |
| | Peter J Vrettakos | 3739 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *25-45 and 64-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24,46-63 and 78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The Applicant has filed an Amendment dated 5-13-05 in which changes were made to independent claims 1 and 46 with language toward the tissue penetrability of the microwave antenna. Claim 78 is newly added.

In response, the Examiner has presented new rejections (with the same art used in the prior office action) in which the tissue penetrability of the microwave antenna of Edwards US 5,964,755 is integrated into the cooling jacket – microwave antenna assembly disclosed by Storm (4,140,130).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 1-16, 19-24, 46-56, and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storm (4,140,130) in view of Edwards (5,964,755).**

*Storm neglects to expressly mention a tissue penetrating microwave antenna.*

Edwards discloses an introducer (14) for use with a microwave antenna (patented claim 15). The expandable member 12 is analogous to Storm's "cooling jacket". This disclosure is also construed as a tissue penetrating microwave antenna (patented claim

15, energy delivery device – 10 in figure 1a; element 14 can be designated as being part of the microwave antenna). In other words, element 14 (an introducer) being part of the microwave antenna (energy delivery device 10 – patented claim 15) means that element 10 is capable of tissue penetration (see col. 4:19-23). The Examiner asserts that tissue penetration includes entry into body lumens such as the cervix.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards by an introducer for use with a microwave antenna. The motivation would be to provide a means to place an *internally placed* (penetrating) microwave antenna such as that in Edwards, while retaining the cooling abilities of the Storm device.

*Note: the remainder of the rejection includes Storm exclusively.*

Independent claims 1 and 46

Storm discloses a cooling system for use with a microwave antenna (col. 2:28-32; col. 7:49-53; 12, figure 2; *note that element 40 in figure 9 is an analogue of element 12*), comprising:

a cooling jacket (30, col. 10:2-6, another analogue is the structure enveloping chamber 61) adapted to at least partially surround a microwave antenna, wherein the cooling jacket is further adapted to retain a cooling fluid (26a, figure 6) therein such that at least

a portion of the microwave antenna is in fluid contact with the cooling fluid (col. 10:9-13).

A cooling sheath system for use with a microwave antenna, comprising:
a first tubular member (57, figure 9) defining an antenna lumen therethrough, the first tubular member being adapted to at least partially surround (col. 11:17-20) the microwave antenna (40); a second tubular member (55) positioned about a length of the first tubular member; and a fluid channel (59) defined between the first tubular member and the second tubular member, wherein the fluid channel is adapted to retain a cooling fluid (in 61) therein and envelope at least a portion (43) of the antenna lumen.

Dependent claims (parentheticals refer to Storm)

2. The system of claim 1 further comprising at least one inlet lumen (59) and at least one outlet lumen (60) each in fluid communication with the cooling jacket for circulating the cooling fluid therethrough.

3. The system of claim 2 wherein a distal end of the inlet lumen (59) is positioned near or at a distal end (43) of the microwave antenna (depicted in figure 9).

4. The system of claim 2 wherein a distal end of the outlet lumen (60) is positioned proximally (slightly) of the microwave antenna distal end (43) as depicted in figure 9.

5. The system of claim 2 wherein the inlet lumen (59) is defined along an outer surface (figure 9 shows that element 59 is connected **but separate** from the cooling jacket which envelops chamber 61) of the cooling jacket (structure that envelops chamber 61 in figure 9).

6. The system of claim 2 wherein the inlet lumen (59) is defined within a wall (figure 9 shows that element 59 is connected within a wall to the cooling jacket permitting inflow of cooling fluid) of the cooling jacket (depicted in figure 6 – shows the device's distal cross-section).

7. The system of claim 1 further comprising a tip (53, dielectric wall, figure 9) at a distal end of the cooling jacket (envelops chamber 44 in figure 9).

8. The system of claim 7 wherein the tip is tapered (element 53 "tip" is curved and therefore can be characterized as "tapered" in the context depicted in figure 9).

9. The system of claim 7 further comprising a power generator (18, figure 1) in electrical communication with the tip.

10. The system of claim 7 wherein a distal end of the microwave antenna (12/40) is securable (col. 11:13-17, elements 55 and 56 in figure 9) to a proximal portion of the tip (53).

11. The system of claim 10 wherein the tip (53) is adapted to be in electrical communication with the distal end (51) of the microwave antenna. Figure 9 shows that elements 51 and 53 overlap and are consequently in electrical communication at the distal most point of the device depicted.

12. The system of claim 1 further comprising a handle assembly (see the valve in figure 1 attached to the tubular element 28) for attachment to a proximal end (tubular element 28 extends to element 26/59 which contacts the proximal wall of the cooling jacket) of the cooling jacket.

13. The system of claim 12 wherein the handle assembly defines (inherent to the design of a flow control valve) at least one lumen therethrough which is in fluid communication (through element 28) with the cooling jacket.

14. The system of claim 1 further comprising a pump (col. 6:60-65) for circulating the cooling fluid through the cooling jacket.

15. The system of claim 1 wherein the cooling fluid comprises a liquid, gas, or combination thereof (again, see col. 6:60-65).

16. The system of claim 15 wherein the liquid comprises water or saline (col. 6:52-58).

20. The system of claim 1 wherein the cooling jacket is configured in length (the cooling jacket which envelops chamber 61 in figure 9 is the same length as element 43) to match a radiating portion (43) of the microwave antenna. Length is defined here as the distance along the device's longitudinal axis.

21. The system of claim 1 wherein the cooling jacket defines at least a first (44) and a second region (61) adjacent to and separate from one another, the first region being adapted to retain the cooling fluid from a first source (26a in figure 6) in fluid contact with a first portion (inside of element/wall 43) of the microwave antenna, and the second region being adapted to retain cooling fluid from a second source (36a in figure 6) in fluid contact with a second portion (outside of element/wall 43) of the microwave antenna.

22. The system of claim 21 wherein the cooling fluid from the first source is maintained at a first temperature and the cooling fluid from the second source is maintained at a second temperature. Note: because the sources (26a and 36a) are separate it is inherent that they could be maintained at different temperatures. Also see col. 10:12-15.

23. The system of claim 21 wherein the cooling jacket defines a plurality of additional regions (44, 61) adjacent to and separate from one another. Also see figures 11,13,14 which show numerous cooling jackets (74).

24. The system of claim 1 wherein the cooling jacket defines at least a first (44) and a second (61) region adjacent to and separate from one another, the first region (44) being adapted to retain the cooling fluid from a first source (26a) in fluid contact (see figure 9) with a first portion (inside of wall 43) of the microwave antenna, and the second region (61) being adapted to retain cooling fluid from the first source (see next sentence) in fluid contact with a second portion (outside of wall 43) of the microwave antenna. Storm discloses that the separate regions of cooling fluid may come from the same source in the disclosure found in col. 10:9-13, specifically, "may be the same as that circulated through electrode means[.]"

47. The system of claim 46 further comprising at least one inlet lumen in fluid communication with the fluid channel.

48. The system of claim 47 wherein a distal end of the inlet lumen is positioned near or at a distal end of the fluid channel.

49. The system of claim 47 further comprising at least one outlet lumen in fluid communication with the fluid channel.

50. The system of claim 49 wherein a distal end of the outlet lumen is positioned near or at a proximal end of the fluid channel.

51. The system of claim 46 wherein the second tubular member (55) is coaxially positioned about the length of the first tubular member (the cross-section of figure 9 would show this).

52. The system of claim 46 wherein a distal end of the first tubular member and a distal end of the second tubular member are attached (56) together.

53. The system of claim 46 wherein a proximal end (where 50 points in figure 9) of the second tubular member (55) is attached (through 56) along an outer surface of the first tubular member (57).

54. The system of claim 46 wherein the antenna lumen (enveloped by 57 in figure 9) is adapted to conform to a shape of the microwave antenna (in the sense that the antenna rests securely inside the lumen enveloped by element 57).

55. The system of claim 46 wherein the fluid channel (59) is concentrically defined between the first tubular member (57) and the second tubular member (55) (the cross-section of figure 9 would show this).

56. The system of claim 46 further comprising a pump (col. 6:60-65) in fluid communication with the fluid channel.

61. The system of claim 46 further comprising a hub (41, figure 9) connected to a proximal portion (see figure in which the analogue (adjacent to wires) of element 41 is ultimately connected to element 19) of the system. Note: "hub" is a broad term simply defined as "a center of activity or interest; a focal point."

62. The system of claim 61 further comprising an adjustable securing member (58, figure 9, col. 11:19-21) positioned on the hub which is adapted to inhibit movement of at least the first tubular member (57) relative to the microwave antenna (40).

63. The system of claim 46 wherein the antenna lumen is adapted to surround a shaft portion of the microwave antenna (this arrangement is depicted in figure 9).

**Claims 18, 57-60, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storm in view of Edwards (5,964,755) and further in view of Uthe (5,829,519).**

*Storm/Edwards neglect to expressly mention the materials used in the design of their invention's tubular members.*

Uthe discloses a microwave antenna (the use of the antenna is not relevant to this rejection) suggestively made up of ceramics, polymers, metals, as well as a temperature sensor (patented claim 12 and col. 3:35-40).

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards (5,964,755) and further in view of Uthe by including a temperature sensor as well as choosing from different materials to comprise the device. The motivation would be to provide temperature feedback to the user, as well as choices of commonly known material types, which could make an effective microwave antenna.

**Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Storm in view of Edwards (5,964,755) and further in view of Edwards et al. (5,281,217).**

*Storm neglects to expressly mention carbon dioxide use for cooling purposes in a microwave antenna.*

Edwards discloses carbon dioxide use for cooling purposes in a microwave antenna.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Storm in view of Edwards (5,964,755) and further in view of Edwards by including carbon dioxide as a means to cool. The motivation would be to provide a well-known choice of cooling gas in microwave antennas.

### *Response to Arguments*

Applicant's arguments with respect to claims 1-24,46-63, and 78 have been considered but are moot in view of the new ground(s) of rejection. Again, the rejections in the case have changed to address amendments, but the art is the same. It would have been obvious at the time of the invention to integrate the tissue penetrating antenna in Edwards into the Storm cooling jacket antenna assembly. The motivation would be to increase the applicability of the Storm cooling jacket antenna assembly from external applications to internal applications. This is no great cognitive leap because the Storm patent actually addresses treatment of internal tissue (with tumor – 14 – see figure 1). Further, a related tissue penetrating microwave antenna (another Edwards patent) has been asserted (US 5,951,547).

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
May 22, 2005

MICHAEL PEFFLEY
PRIMARY EXAMINER